ORIGINAL ARTICLE

A Comparative Study on Ventral Dartos Flap Vs Tunica Vaginalis Flap in Hypospadias Repair, Decreasing the Incidence of Fistula Formation

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ABSTRACT

Objective: To compare the effectiveness of the Tunica Vaginalis Flap (TVF) and the Ventral Dartos Flap (VDF) in reducing fistula formation following distal hypospadias repair in pediatric patients.

Study Design: Quasi-experimental study.

Place and Duration of Study: This study was conducted at the Department of Paediatric Surgery, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan from January 2023 to December 2024.

Methods: A total of 100 patients under eight years of age with distal hypospadias were recruited. Patients were randomly divided equally into two groups (TVF vs VDF), using a random numbers table. Data was analyzed using SPSS version 27, with chi-square tests for categorical variables and independent t-tests for continuous variables with significance set at $P < 0.05$.

Results: The mean age of all patients was 2.46±1.210 years, while the mean weight was 11.47 ± 3.115 kg, and were comparable between groups. During the 6 months follow-up, a total of 25% (N=25 out of 100) patients developed Urethro Cutaneous Fistula (UCF), with 13% (N=8) in the TVF group and 34% (N=17) in the VDF group, indicating a statistically significant reduction in fistula formation with tunica vaginalis flap (P=0.038). The superior vascularity and independent blood supply of TVF likely contributed to improved wound healing and fewer UCF.

Conclusion: In this study, TVF provides a more trustworthy neourethral coverage than VDF in distal hypospadias repair, particularly lowering UCF incidence. These results justify the preferred use of TVF for neourethral coverage to improve surgical outcomes. However, the choice between the two techniques may depend upon the operating surgeon's preferences and patient-specific factors. Further large-scale studies with extended follow-up are recommended to validate these results.

Keywords: *Congenital Abnormalities, Fistula, Hypospadias, Morbidity, Surgical Flaps*.

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Introduction

Hypospadias is a congenital malformation characterized by the urethral opening being positioned on the ventral side of the penis. It is among the most frequently observed genital abnormalities in male newborns, with an estimated incidence of 1 in every 200 to 1 in every 300 live births.[1] The goal of surgery is to create a straight and well-vascularized neourethra while minimizing complications. Various surgical procedures, single-stage or two-stage procedures, are in practice, depending upon the hypospadias characteristics, such as the meatal location and degree of chordee. Urethrocutaneous Fistula (UCF) is a critical complication in hypospadias surgery, leading to urinary leakage and potential long-term morbidity.[2] Among the factors that influence surgical approaches and repair, one of the most important

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factors is the choice of flap material used to cover the neourethra. Various vascularized flaps may be used for this purpose, including dorsal or ventral penile/preputial dartos, tunica vaginalis, and periurethral corpus spongiosum. Still, the Ventral Dartos Flap (VDF) and Tunica Vaginalis Flap (TVF) are commonly employed.[3]

The VDF is harvested from the ventral aspects of the penile shaft and is a pliable, well-vascularized cover to the neourethra, which is believed to reduce the risk of fistula formation. Whereas for the TVF, the testicle is delivered and its tunica vaginalis (a double-layered serous membrane) dissected off the testis and spermatic cord, to cover the neourethra.[4] The choice between the VDF and the TVF in hypospadias repair remains a topic of debate among Urologists and Pediatric Surgeons. While in the local setup, a comparison between the two flaps in terms of post-operative complications is lacking. The rationale of this study is to compare the effectiveness of the two innovative flaps in reducing fistula incidence.

Although surgical methods have continued to evolve, UCF remains a persistent complication in hypospadias repair, adversely impacting both clinical outcomes and the patient's quality of life. The objective of this study is to compare the incidence of UCF formation following hypospadias repair using either the VDF or the TVF as a second-layer interposition tissue, and hence identify the most effective approach for reducing complications and enhancing recovery. Furthermore, this represents the inaugural research in Pakistan to compare the two flap techniques. Therefore, a head-to-head comparison of VDF and TVF in hypospadias repair could provide valuable evidence to guide surgical decision-making and potentially improve patient outcomes.

Methods

This study was conducted at the Department of Paediatric Surgery, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan from January 2023 to December 2024. A total of 100 patients were recruited. Mean duration of follow up was 6 months. Ethical approval was taken from hospital Ethical Committee vide letter no: A28/ER/18/14, dated: 12th October 2022. Sampling technique was non-probability consecutive sampling. Anticipated Population mean for TVF = 16% and for VDF = 34%, Sample Size (N) = 50 patients in each group. Patients who have concomitant congenital anomalies and recurrence were excluded from the study to control bias and confounding factors. Ethical issues like consent, privacy of the patient and financial problems were properly addressed. All operations were performed under general anesthesia. A stay suture was inserted on the dorsal surface of the glans to help with phallus traction and subsequent fixation of the urethral stent. A circumferential skin incision was placed 1–2 mm proximal to the urethral meatus (Coronal & subcoronal), followed by degloving of the penile shaft down to the penoscrotal junction. Artificial erection was created, and the degree of chordee was measured and corrected intraoperatively. Parallel longitudinal incisions were made extending from the hypospadiac meatus to the glans, allowing the urethral plate to be mobilized from the glanular wings. A Midline relaxing incision was given in the urethral plate in all patients to achieve a target width of 14 mm with tenotomy scissors. A 6 French feeding tube was placed in the bladder as a urinary stent and secured with polypropylene 4/0. Tubularization was done in two layers. The initial layer was closed using interrupted subcuticular sutures, followed by a second layer secured with continuous subepithelial stitches, both using 6-0 Vicryl. This technique resulted in the formation of a well-calibrated, oval-shaped neo meatus.

In the VDF group, a well-vascularized ventrally based dartos flap was carefully dissected and mobilized bilaterally from the urethral corporal groove to provide coverage over the neourethral suture line, which was reinforced using 6-0 Vicryl sutures. (Figure 1). To maintain the penile shaft in place, thin dressing was applied. An open dressing was used on the second postoperative day. IV antibiotics (3rd Generation Cephalosporin) were discontinued on 3rd post op day and replaced with the appropriate oral antibiotics (3rd Generation Cephalosporin). The urethral stent was removed on 7th post-operative day. The patients were discharged after removal of urethral stent.

In the TVF group, neourethra coverage was obtained by harvesting tunica vaginalis flap from either right

or left testis. The testis and the spermatic cord were delivered into the operative field. Traction sutures

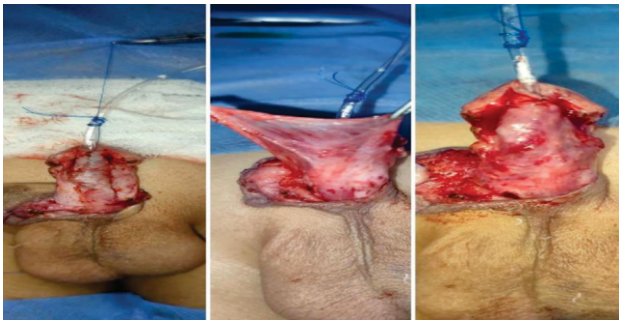

Fig.1: a. Neo Urethra Constructed b.VDF Harvested & Mobilized c. VDF Covering Neo Urethra

were placed on the lateral edges of the tunica vaginalis. A transverse incision was made in the tunica vaginalis proximal to testis/epididymis and adequate flap (at least 5 mm wide and long enough to completely cover the neourethra, prevent post op glans tethering and testicular ascent) is raised from spermatic cord (Figure 2). The graft was secured over neourethra using vicryl 6/0 in an interrupted fashion. The rest of the technique was same as detailed in the VDF group.

The data was analyzed using SPSS version 27, which was implemented. Mean and Standard Deviation (SD) were calculated for categorical variables like age and weight in both groups. The quantitative variables

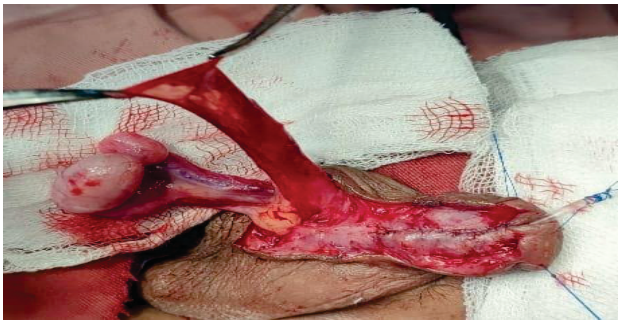

Fig.2: Well vascularised, double membranous TVF is harvested and ready to cover neourethra

were expressed as frequency or percentages. Primary outcomes, such as successful surgery (No Fistula) and complication (Fistula formation) at 6 months follow-up, were recorded and compared using the chi-square test, keeping *P*-value <0.05 as statistically significant.

Results

A total of 100 cases fulfilling the inclusion/exclusion criteria were enrolled to compare TVF used for reconstruction of the distal urethra with VDF.

The age demographic data showed that the mean age of the study population was 2.94 ± 1.69 years, with ages ranging from 1 to 8 years. The average weight was 13.05 ± 3.16 kilograms, with a minimum of 8.7 kg and a maximum of 22.0 kg, as shown in Table 1.

Table-1: Descriptive statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age in Years	100	1	8	2.94	1.692
Weight in Kgs	100	8.70	22.00	13.0470	3.15753

Table 2: Fistula formation after 6 months (N=100)

		Type of Procedure				Total	
		TVF		VDF			
		N	%	N	%	N	%
UCF	No	42	84.0%	33	66.0%	75	75.0%
UCF	yes	8	16.0%	17	34.0%	25	25.0%
Total		50	100.0%	50	100.0%	100	100.0%

Table 3: Comparison of age and weight between surgery groups

Variable	*t*-value	df	Mean Difference	Interpretation
Age	-0.129	98	-0.044 years	Not significant
Weight	-0.318	98	-0.202 kg	Not significant

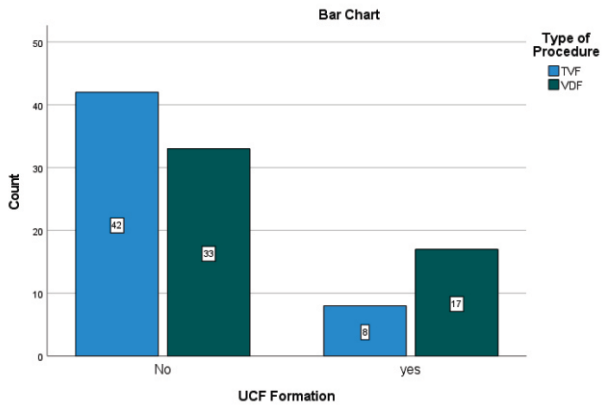

Fig.3: Graphical distribution of UCF in type of surgery performed (TVF vs VDF)

The highest proportion of patients was observed at 2 years of age, comprising 31.0% of the total cohort. This was followed by 3-year-olds (18.0%), and 4- and 5-year-olds, each accounting for 11.0% of cases. Ages 6 to 8 represented a smaller portion of the study population.

After a 6-month follow-up, UCF developed in 16.0% of patients in the TVF group, compared to 34.0% in the VDF group (Figure 3). This indicates a notably lower fistula rate in patients who underwent the tunica vaginalis flap repair, suggesting a potential clinical advantage of TVF in minimizing postoperative complications. (Table 2).

Table 4: Association between type of surgery and UCF formation

Test	Value	df	*P*-value	Interpretation
Pearson Chi-Square	4.320	1	0.038	Significant association
Likelihood Ratio	4.396	1	0.036	Supports Chi-square result
Linear-by-Linear	4.277	1	0.039	Indicates linear trend
Cramer's V	0.208	-	0.038	Small to moderate effect size

Independent samples t-tests were performed to check the difference in age and weight between the two surgical groups (TVF vs. VDF), which shows mean age t = -0.129 and weight t = -0.318, indicating that neither age nor weight differed significantly between the two groups. (Figure 3). The degree of freedom (df) of 98, which indicates a sufficient sample size for fundamental analysis. Although no significant differences were observed in age or weight, the results reinforce the central finding that the surgical technique plays a key role in fistula prevention. (Table 3).

The outcome of interventions, in terms of No Fistula (successful) or Fistula formation (complication), was documented after 6 months in both groups. A chi-square test was conducted to assess the association between the type of surgical technique (TVF vs. VDF) and the occurrence of UCF. The analysis revealed a statistically significant relationship between the two variables (N = 100), Pearson value = 4.320, *P* = 0.038. This suggests that the incidence of UCF varied significantly depending on the surgical method used. Specifically, patients who underwent the TVF technique demonstrated a different UCF rate compared to those who received the VDF repair. The finding was further supported by the likelihood ratio = 4.396, *P* = 0.03, and the linear-by-linear association = 4.277, *P* = 0.039, indicating consistency across statistical approaches. In addition to statistical significance, the strength of the association between the type of surgical procedure and UCF formation was assessed using Cramer's V. The analysis yielded a Cramer's V value of 0.208, *P* = 0.038, indicating a mild to moderate association between the surgical technique (TVF vs. VDF) and the occurrence of UCF, as shown in the Table 4 below. Collectively, the chi-square test and Cramer's V support a statistically significant association between the type of surgical procedure and the incidence of UCF, underscoring the relevance of surgical choice in improving patient outcomes.

Discussion

Hypospadias results from arrested development of the ventral genital tubercle (GT) during the critical 'masculinization window' (6–16 weeks of gestation). Although its exact cause remains unclear, it is considered multifactorial, involving genetic and hormonal factors, placental function, maternal health, and environmental exposures such as endocrine disruptors. Surgical correction typically involves degloving the GT to assess corpus spongiosum division and degree of curvature, selecting an appropriate urethroplasty technique based on urethral plate quality, tissue availability,

glans morphology, and reconstruction length, and redistributing penile skin to cover the straightened GT. Long-term evaluation of functional and cosmetic outcomes is vital, particularly as pediatric urological reconstructions are performed on anatomically developing organs.[5] UCF is one of the most concerning complications following hypospadias repair, with incidence rates ranging from 5% to 45% and often leading to the need for corrective surgery.[6]

The decision to perform an appropriate technique for hypospadias repair largely depends on the surgeon's expertise, training background, and the specific characteristics of the hypospadias. Optimal surgical outcomes are typically achieved by adhering to fundamental microsurgical principles — including appropriate case selection, use of magnification tools, fine suture techniques, age-appropriate timing of surgery, and diligent postoperative management.[7]

Our data demonstrated a significant difference in UCF incidence between the two groups, which aligns with several recent studies that have examined the efficacy of these two flaps. The difference in outcomes is noteworthy given the known risks associated with each flap. The VDF, while widely used due to its proximity to the surgical site and its ease of harvesting, can sometimes lead to complications like UCF, particularly when tension exists at the suture line or the flap experiences ischemia. Although it provides a local, well-vascularized tissue for coverage, the limited mobility and thinness of the flap in some patients may compromise its protective function.[8] Furthermore, in cases where the dartos fascia is scarred or poorly developed, the reliability of VDF as a reinforcing layer may be reduced, increasing the risk of wound dehiscence and fistula formation.

In contrast, TVF, being a vascularized flap that is independent of the overlying skin, provides a more reliable barrier to prevent fistula formation, thus reducing the chances of recurrence. Its robust blood supply enhances tissue healing and offers better protection over the neourethra, particularly in cases where local tissue quality is compromised or when previous repairs have failed. TVF's flexibility and thickness make it a suitable option for both primary and re-operative hypospadias surgeries. Moreover, because it is harvested from the tunica vaginalis of the testis, it avoids additional trauma to penile skin, preserving cosmetic outcomes. These advantages have led many surgeons to consider TVF a preferred choice in proximal and complex cases where the risk of complications is higher.[9]

The findings of our study agree with a meta-analysis conducted by Yang H et al. who reviewed various complications associated with hypospadias repair, specifically focusing on the formation of UCF.[10] In their analysis, the incidence of UCF was reported as 2.6% in the TVF group compared to 7.8% in the VDF group, which corroborates our results. They concluded that TVF's superior blood supply, coupled with its independent nature from the external skin, helped prevent the breakdown of sutures and the formation of fistulas. Similarly, a study done in Dhaka in 2024 demonstrated that by using a TVF in TIPU for distal penile hypospadias compared to the dartos fascia technique, reduced complication rates. TVS demonstrated a reduced rate of wound infection (14.3% vs. 45%) and reduced incidence of UCF formation (14.3% vs. 45%), suggesting it as a more effective soft tissue coverage option.[11]

UCF was identified as a direct consequence of wound dehiscence in a couple of cases. A common factor contributing to UCF formation is inadequate tissue healing, which may be reinforced by local infection, excessive tissue tension, or insufficient vascularity at the surgical site.[12] In the VDF group, the relatively higher rates of wound dehiscence and subsequent fistula formation can be attributed to the potential impairment of the blood flow to the penile skin. This vascular compromise can cause delayed wound healing, which may not only contribute to dehiscence but also provide a pathway for the formation of UCF.[13] Similar results have been reported in existing literature in which the TVF serves as a practical support in complex hypospadias repairs. Its ease of harvest, availability, and rich blood supply contribute to a notable reduction in postoperative fistula rates and fewer recurrence rates compared to other techniques, including VDF.[14]

Our findings highlight the importance of careful surgical technique. Tension-free suturing and precise tissue handling, especially in the TVF group, helped reduce complications. Combined with attentive postoperative care, this led to fewer cases of UCF.[15] According to a 2022 study by Wang X et al. The tunica

vaginalis flap technique offers multiple advantages, including a single-stage procedure that ensures better cosmetic results at a lower cost. It is considered a safe, effective, and simpler alternative compared to earlier surgical approaches.[16] In a meta-analysis done by Moran GW et al., it was concluded that placing a barrier layer between the neourethra and skin has been linked to reduced rates of postoperative urethro cutaneous fistula (UCF) after hypospadias repair with TVF.[17]

Contrary to these studies a study done by Ahmed F et al. comparing the two techniques concluded that there was no significant difference between the two (TVF vs VDF) in achieving desired outcome (90.9% for TVF and 80 % for VDF, *P* value=0.99). This highlights the importance of careful patient selection and meticulous surgical technique when opting for VDF in hypospadias repair.[18] Alternatively, some studies propose that TVF is better suited exclusively for mid and distal hypospadias, offering favorable outcomes in such cases, and the dorsal preputial dartos flap is suitable for distal hypospadias for better results.[19]

While a few studies present neutral outcomes, the majority of available evidence concurs with our findings that TVF is superior to dartos due to its lower complication rate, better vascularity, greater length, and suitability for prepucioplasty, despite the dartos flap's ease of use without scrotal dissection. Both techniques showed excellent outcomes, though UCF was slightly lower with TVF. Evidence suggests that TVF is consistently associated with a lower rate of UCF compared to VDF in both initial and recurrent hypospadias surgeries.[20] Although it may take more time to perform, TVF offers better protection against fistula formation and improved cosmetic results.[21]

In summary, the present study reinforces evidence favoring the use of the TVF flap in reducing urethrocutaneous fistula rates, particularly in distal hypospadias. While most reviewed studies are consistent with our findings, a few reports neutral outcomes reflecting the complexity and variability in surgical decision-making. Despite these differences, our data contributes valuable insight to the ongoing discourse on flap selection. Further prospective, multi-center studies are warranted to establish more definitive clinical guidelines and validate long-term outcomes.

Further research with a larger sample size and extended follow-up periods is required to reinforce these findings and inform evidence-based clinical decisions.

Conclusion

In conclusion, TVF's robust and independent blood supply provides more trustworthy neourethral coverage than VDF in distal hypospadias repair, particularly reducing UCF incidence. These results warrant the preferred use of the tunica vaginalis flap in hypospadias repair for an improved and enhanced surgical outcome. However, the choice between the two flaps may depend upon the operating surgeon's preference and patient-specific factors.

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Author Contributions

RA: Writing the original draft, proofreading, and approval for final submission
YA: Conception and design of the work
AA: Revising, editing, and supervising for intellectual content
MSJ: Manuscript writing for methodology design and investigation
MHR: Validation of data, interpretation, and write-up of results
SJ: Data acquisition, curation, and statistical analysis